

WO 2005/053691

PCT/DK2004/000841

10

CLAIMS

1. A nicotine delivery product comprising an intimate mixture of the reaction product of a nicotine/cation exchange resin complex and an organic polyol.
- 5 2. A nicotine delivery product according to claim 1, characterized in that the ratio of resin to polyol is from about 1:1 to about 10:1, preferably from 2:1 to 8:1 and most preferably about 2.4:1
- 10 3. A method for preparing a nicotine delivery product said method comprising (a) mixing an aqueous suspension of a nicotine/cation exchange resin complex with an organic polyol or an aqueous solution thereof, and (b) removing water from the mixture to produce said nicotine delivery product.
- 15 4. A method for preparing a nicotine delivery product said method comprising (a) mixing an aqueous solution of nicotine with a cation exchange resin thereby forming a nicotine/cation exchange resin complex, (b) admixing with said complex of step (a) in aqueous suspension an organic polyol or an aqueous solution thereof to form an aqueous slurry of nicotine/cation exchange resin complex incorporating polyol, and (c) removing water from said slurry to produce said nicotine delivery product.
- 20 5. A method according to claim 3 or 4 wherein the cation exchange resin is selected from the group consisting of
 - (i) a methacrylic, weakly acidic type of resin containing carboxylic functional groups
 - (ii) a polystyrene, strongly acidic type of resin containing sulfonic functional groups, and
 - (iii) a polystyrene, intermediate acidic type of resin containing phosphonic functional groups.
- 25

BEST AVAILABLE COPY

WO 2005/053691

PCT/DK2004/000841

11

6. The method according to claim 5 wherein the cation exchange resin is a methacrylic, weakly acidic type of resin containing carboxylic functional groups.
7. The method according to claim 6 wherein the cation exchange resin is polacrilex (Amberlite® IRP64).
8. A method according to any one of claims 3-7 wherein the organic polyol is a non-toxic C₂ to C₁₂ linear or branched hydrocarbon having at least 2 hydroxy groups.
9. A method according to claim 8 wherein the organic polyol is selected from the group consisting of 1,2-propanediol, 1,3-propanediol, 1,6-hexanediol, glycerol and sorbitol.
10. A method according to any one of claims 3-7 wherein the organic polyol is a non-toxic C₅ to C₁₂ cyclic or heterocyclic hydrocarbon having at least 2 hydroxy groups.
11. A method according to claim 10 wherein the organic polyol is selected from the group consisting of hexahydroxy cyclohexane (Inositol) and mono- and disaccharides.
12. A method according to claim 11 wherein the organic polyol is glucose, fructose or sucrose.
13. The method according to any one of claims 3-12, wherein the concentration of nicotine in said aqueous solution of nicotine is from about 5% by weight to about 50% by weight.
14. The method according to any one of claims 3-13, wherein the ratio of cation exchange resin to nicotine is from 1:1 to 10:1.
15. The method according to claim 14, wherein the ratio of cation exchange resin to nicotine is from 2:1 to 6:1.

BEST AVAILABLE COPY

WO 2005/053691

PCT/DK2004/000841

12

16. The method according to claim 14, wherein the ratio of cation exchange resin to nicotine is about 4:1.
17. The method according to any one of claims 3-16, wherein the ratio of cation exchange resin to organic polyol is from 1:1 to 10:1.
- 5 18. The method according to claim 17, wherein the ratio of cation exchange resin to organic polyol is from 2:1 to 8:1.
19. The method according to claim 17, wherein the ratio of cation exchange resin to organic polyol is about 2.4:1.
- 10 20. A method for preparing a nicotine delivery product having a nicotine release rate of at least 80 % over a 10 minute period, said method comprising
- (a) mixing an aqueous solution of nicotine with a cation exchange resin selected from the group consisting of
- (i) a methacrylic, weakly acidic type of resin containing carboxylic functional groups,
- 15 (ii) a polystyrene, strongly acidic type of resin containing sulfonic functional groups, and
- (iii) a polystyrene, intermediate acidic type of resin containing phosphonic functional groups
- thereby forming a nicotine/cation exchange resin complex,
- 20 (b) admixing with said complex of step (a) an organic polyol or an aqueous solution thereof to form an aqueous slurry of nicotine/cation exchange resin complex incorporating polyol, and
- (c) removing water from said slurry to produce said nicotine delivery product.
- 25 21. A nicotine delivery product obtainable by a method according to any one of claims 3-20.

BEST AVAILABLE COPY

WO 2005/053691

PCT/DK2004/000841

13

22. A chewable gum composition comprising a chewing gum base and a nicotine delivery product as defined in claims 1-3 or prepared by the method defined in any one of claims 3-21 substantially uniformly distributed in said chewing gum base.

BEST AVAILABLE COPY